Medical Parents/Legal Guardian Informed Consent For Minor

North Dakota Department of Human Services
Information for People Who Take Part in Research Studies

The following information is being presented to help you/your child/ward decide whether or not your child/ward wants to be a part of a research study. Please read carefully. Anything you do not understand, ask the doctor.

Title of Study:

Doctor in Charge of Study:

Other Doctors or Staff:

Study Location(s):

Sponsor:

General Information about the Research Study

The purpose of this research study is to…*(explain completely)*

The time your child/ward will need to spend in this research study will be approximately:

The number of people that might participate in this study is:

Screening Phase *(Please delete if not applicable.)*

If you decide that your child/ward should take part in this study, you will be required to review this informed consent, discuss the study and your child's/ward's possible participation with the study doctor and study nurse. If you are interested in having your child/ward take part in the study, this informed consent must be signed before any study-related test or procedure can be done. After signing this informed consent, medical tests will be completed to help determine if your child/ward meets the requirements to be in the study. These tests which are called "screening tests" are described below.

(Please list any screening tests that will be done.)

Plan of Treatment

Your child's/ward's **regular medical treatment** will not actually be part of the research study, but will prepare your child/ward for the study. This regular treatment will include:

(Describe pre-treatment procedures if applicable; such as drug-washout period, discontinuation of certain medications, changes in certain day to day functions, etc. Also describe treatment, e.g., drug, dosage form, route of administration, radiation type and dose; special diets; biopsies, operations; frequency, how often/day, absolute duration of treatment).

The **experimental treatment** that your child/ward will receive by taking part in this research study is:

(Describe drugs, devices, procedures that are not part of standard treatment, e.g., experimental drugs, dosage forms, radiation types and doses; special diets; biopsies/operations, extended hospitalization; how often/day, absolute duration of treatment).

Use of Placebo Drug *(Delete this section if you are not using a placebo.)*

Some research studies compare a placebo's effects with effects of *(experimental drug)*. A placebo is an inactive compound that looks exactly like the *(experimental drug)* but will probably have no effect on your child's/ward's body. This research study has a placebo group.

Your child's/ward's chance of receiving the placebo instead of *(experimental drug)* is: *(State chances here.)*

The placebo might cause your child/ward harm if there is a regular treatment for the disease, which your child does not receive, because your child/ward is taking the placebo. This possibility *(applies/does not apply)* to your child/ward because regular treatment (*is/is not)* available for your child's/ward's disease.

Storage of Blood and/or Tissue Samples *(Delete this section if it does not pertain to you.)*

Some of your child's/ward's blood and/or tissues that are collected during this research study may be used by the study doctor and/or the drug company to increase their knowledge of the disease and the effects of *(experimental drug)*.

By participating in this research, blood and/or other body tissues will be removed from your child/ward, with the tissue and cells analyzed and used by the Investigators and/or sponsors. Your child's/ward's cells or tissue may be used for the commercial development of new therapies or treatment for disease. By signing this consent form, you agree to allow the Investigators to analyze and use your child's/ward's tissue(s) as described for the purpose stated.

Genetic Testing of Blood and/or Tissue Samples *(Delete this section if it does not pertain to you.)*

Genetic research is an important way to try to understand the role of genes in human disease. There are several things you should know before allowing your

child's/ward's tissues, cells or blood to be studied or to be stored for future study.

Genetic research serves a number of purposes. These include medical knowledge, public health tracking and the development of new drugs, tests and treatments. Any drugs, tests or treatments that are developed might make money for the university, but neither you nor your child/ward will share in any profits the university might receive from such commercial products. You will not be paid for the use of your child's/ward's blood or tissue, or the information they contain. Information gained from tests of your child's/ward's genetic material (or DNA) will be used for research.

*(If the samples will be <u>unlinked</u> to the patient's identity, use the following paragraphs. **Please Note**: An initial line is provided at the end of the section so that the parent/guardian can indicate that he/she chooses to have genetic testing done on the child/ward and that the genetic testing has been adequately explained to him/her.)*

1. Once the sample is taken, it will forever be separated or "unlinked" from your child's/ward's name. This will protect your child's/ward's confidentiality and anonymity; it will also have other consequences:

2. Suppose the scientists discover that your child's/ward's blood sample carries a gene for a disease. Because the sample is anonymous—it is not labeled with your child's/ward's name or any code—the North Dakota Department of Human Services will not be able to provide you with this information. In other words, because the blood sample has been made anonymous, information about it cannot be communicated to you. If you are concerned about a potential genetic disease or problem, you and your child's/ward's doctor might choose to test specifically for it; this would require additional blood or tissue samples. You should discuss this option with your child's/ward's doctor or genetic counselor.

3. Neither can such information be communicated to your family members. Genetic information about your child/ward will often apply (in one degree or another) to family members.

4. Even though your child's/ward's name will not be connected to the tissue or blood sample, other information about your child/ward might still be connected. For instance, information about race, ethnicity, sex, your child's/ward's medical history, and so forth might be available to scientists studying your child's/ward's tissue or blood. Such information might be important for research or public health. It is possible that genetic information might come to be associated with your child's/ward's racial or ethnic group.

5. You can refuse to allow your child's/ward's tissue or blood to be studied or saved for future study. Once you agree to allow scientists to use your child's/ward's tissues, however, it will be impossible for you to withdraw from any research project using your child's/ward's tissue or blood. This is because the samples will have been made anonymous; it will not be possible to find your child's/ward's

sample to withdraw it.

_____

Parent's/Guardian's Initials

(If the samples will be <u>linked</u> to the patient's identity but the patient <u>will not be</u> recontacted, use the following paragraphs. ***Please Note****: An initial line is provided at the end of the section so that the parent/guardian can indicate that he/she chooses to have genetic testing done on the child/ward and that the genetic testing has been adequately explained to him/her.)*

1. Your child's/ward's tissue, cell or blood sample will be stored under your child's/ward's name or a number linked to your child's/ward's name. Your child's/ward's confidentiality will be protected at least to the extent required by law. Your child's/ward's records might be reviewed by government officials or by corporate research sponsors. The North Dakota Department of Human Services collaborates with many other organizations, and information is sometimes shared among them. No information shared with other investigators will include your child's/ward's name or other public identifier, however.

2. Genetic research may affect your child's/ward's ability to get or keep health insurance. For instance, information about your child's/ward's DNA might result in discrimination that would make it difficult for your child/ward to obtain health insurance in the future. You will still be responsible for paying for health care for your child/ward, however, the North Dakota Department of Human Services will not be responsible for such costs, even if care is needed for a condition revealed during research or clinical testing.

3. Genetic information about your child/ward will often apply (in one degree or another) to family members. It is not generally the Department's policy to provide genetic information about your child/ward to your family members. However, certain studies, called "pedigree studies", share such information among family members. For this and related research you will be asked if you are willing to share your child's/ward's genetic information with your family members.

4. In addition to your child's/ward's name, other information about your child/ward might be connected to your child's/ward's blood or tissue sample. For instance, information about race, ethnicity, sex, your child's/ward's medical history, and so forth might be available to investigators studying your child's/ward's tissue or blood. Such information might be important for research or public health. It is possible that genetic information might come to be associated with your child's/ward's racial or ethnic group.

5. It is possible that more tissue or blood samples will be obtained than are necessary for your child's/ward's treatment. That is, investigators might take samples purely for study purposes.

6. Genetic research raises difficult questions about informing you and other parents/guardians of any results, or of future results. Some people want to know what is found out about their child/ward; others do not. The risks of knowing include anxiety and other psychological distress, and the possibility of insurance discrimination. The risks of not knowing what is found include not being aware of the need for treatment. But these risks can change depending on whether there is a treatment or cure for a particular disease, and on how clear the results are. A process called “genetic counseling” is often useful and appropriate when people are learning about their genes. You should ask your child's/ward's doctor or nurse if you would like to learn more about this.

7. In this study, investigators will ***not*** tell you what they find out about your child/ward, nor will they contact you if a test becomes available to diagnose a condition your child/ward might have or later develop. For instance, suppose the investigators discover that your child's/ward's tissue sample carries a gene for a disease. Neither the university nor your child's/ward's doctor will try to contact you or find you to tell you about this gene. While we might not know how to test for a particular disease gene today, we might be able to test for it in the future. The number of genes for which this will be possible in the future is quite large.

8. There are alternatives to notification by investigators. If you are concerned about a potential genetic problem or disease, you and your child's/ward's doctor might choose to test specifically for it; this would require additional blood or tissue samples. You should discuss this option with your child's/ward's doctor or genetic counselor.

9. The presence of a genetic marker does not necessarily mean that a patient will develop a disease. Informing people of all such markers without a medical need can cause unnecessary anxiety. On the other hand, the absence of a marker does not mean that someone will not get the disease. “Genetic diseases” appear as a result of a complex mixture of genes, the environment, behavior and other factors.

10. You have the right to refuse to allow your child's/ward's tissue or blood to be studied or saved for future study. You may withdraw your child/ward from a study at any time, and remove from research use any samples that contain identifiers. This means that while the university might retain the identified samples, they would not be used for research. Samples without identifiers might still be retained for research; a different process or consent form is usually used in such cases.

Parent's/Guardian's Initials

(If the samples will be linked to the patient's identity but the patient may be recontacted, use the following paragraphs. ***Please Note****: An initial line is provided at the end of the section so that the parent/guardian can indicate that he/she chooses to have genetic testing done on the child/ward and that the genetic testing has been adequately explained to him/her.)*

1. Your child's/ward's tissue, cell or blood sample will be stored under your child's/ward's name or a number linked to your child's/ward's name. Your child's/ward's confidentiality will be protected at least to the extent required by law. Your child's/ward's records might be reviewed by government officials or by corporate research sponsors. The North Dakota Department of Human Services collaborates with many other organizations, and information is sometimes shared among them. No information shared with other investigators will include your child's/ward's name or other public identifier, however.

2. Genetic research may affect your child's/ward's ability to get or keep health insurance. For instance, information about your child's/ward's DNA might result in discrimination that would make it difficult for you to obtain health insurance for your child/ward in the future. You will still be responsible for paying for health care for your child/ward, however; the North Dakota Department of Human Services will not be responsible for such costs, even if care is needed for a condition revealed during research or clinical testing.

3. You have the right to refuse to allow your child's/ward's tissue or blood to be studied or saved for future study. You may withdraw your child/ward from a study at any time, and remove from research use any samples that contain identifiers. This means that while the university might retain the identified samples, they would not be used for research. Samples without identifiers might still be retained for research; a different process or consent form is usually used in such cases.

4. Genetic information about your child/ward will often apply (in one degree or another) to family members. It is not generally the Department’s policy to provide genetic information about your child/ward to your child's/ward's family members. However, certain studies, called “pedigree studies”, share such information among family members. For this and related research you will be asked if you are willing to share your child's/ward's genetic information with your family members.

5. In addition to your child's/ward's name, other information about your child/ward might be connected to your child's/ward's blood or tissue sample. For instance, information about race, ethnicity, sex, your child's/ward's medical history, and so

forth might be available to investigators studying your child's/ward's tissue or blood. Such information might be important for research or public health. It is possible that genetic information might come to be associated with your child's/ward's racial or ethnic group.

6. It is possible that more tissue or blood samples will be obtained than are necessary for any treatment. That is, investigators might take samples purely for study purposes.

7. Genetic research raises difficult questions about informing you and other parents/guardians of any results, or of future results. Some people want to know what is found out about their child/ward; others do not. The risks of knowing include anxiety and other psychological distress, and the possibility of insurance discrimination. The risks of not knowing what is found include not being aware of the need for treatment. But these risks can change depending on whether there is a treatment or cure for a particular disease, and on how clear the results are. A process called “genetic counseling” is often useful and appropriate when people are learning about their genes. You should ask your child's/ward's doctor or nurse if you would like to learn more about this.

8. Investigators in this study may try to get in touch with you later to find out about your child's/ward's health in the future, but this is not certain. If you are contacted and want to know what the investigators have learned about your child's/ward's tissue samples, you should understand that the following are the kinds of things the investigators or your child's/ward's health team might tell you:

    a) Information is too sketchy to give you particular details, but you will receive a newsletter informing you about the results of the project.

    b) Your child/ward carries a gene for a particular disease that can be treated.

    c) Your child/ward carries a gene for a particular disease for which there is no current treatment. This news might cause severe anxiety or other psychological distress, depending on the severity of the disease.

    d) Your child/ward carries a gene for a disease and you might consider informing relatives that they too, might carry the gene. It can be very difficult to decide whether to share such information with relatives. Genetic counselors can help sort out the various options in such a case.

Also, for any additional, future research, scientists may contact you with a new consent form giving you more information.

9. There are alternatives to notification by investigators. If you are concerned about a potential genetic problem or disease, you and your child's/ward's doctor might choose to test specifically for it; this would require additional blood or tissue samples. You should discuss this option with your child's/ward's doctor or

genetic counselor.

10. The presence of a genetic marker does not necessarily mean that a patient will develop a disease. Informing people of all such markers independently of medical need can cause unnecessary anxiety. On the other hand, the absence of a marker does not mean that someone will not get the disease. "Genetic diseases" appear as a result of a complex mixture of genes, the environment, behavior and other factors.

Parent's/Guardian's Initials

(The following paragraph should be included in all genetic research studies whether data will be unlinked or linked.)

These are some of the risks and other facts you need to know about genetic research. There might be other risks we do not know about yet. No direct benefits can be promised from your child's/ward's participation, though some people find satisfaction in contributing to scientific knowledge about human genetics.

Benefits of Being a Part of this Research Study

We cannot tell whether your child/ward will benefit from taking *(experimental drug)* because its effects on the disease are not totally understood. On the other hand, by taking part in this research study, your child/ward may increase our overall knowledge of the disease and how to treat future patients. *(Explain any further benefits the sponsor details.)*

Risks of Being a Part of this Research Study

Your child/ward may have unpleasant or harmful side effects from taking *(experimental drug).* The possible side effects of *(experimental drug)* are listed below:

(For each foreseeable research procedure/intervention, describe the immediate and long-term physical, psychological, and social risks/discomforts in order from most likely to occur -- least likely to occur.)

Your child/ward may also have side effects from regular treatment of your child's/ward's disease. This treatment would be *(describe standard treatment*). The possible side effects of this regular treatment are listed below:

(For each foreseeable research procedure/intervention, describe the immediate and long-term physical, psychological, and social risks/discomforts in order from most likely to occur –least likely to occur.)

The study doctors will immediately tell you if during the study they discover that *(experimental drug*) causes other new and unknown side effects. If the new findings make it unwise for your child/ward to continue, the doctors will stop the treatment. Your child/ward will then be offered other suitable treatment for the disease.

Alternatives of Being Part of this Research Study

Alternatives of being part of this research study is/are: *(list)*

Risk to Unborn Children (*Delete this section if you are not including children vulnerable to pregnancy or impregnation.)*

Female Subjects

It is possible that *(experimental drug*) may cause unknown side effects on unborn children now or in the future due to exposure in the womb or there may be a risk to your daughter's/ward's child if breast feeding. If your daughter/ward is pregnant, becomes pregnant, or is breastfeeding while taking part in this research study, tell one of the study doctors immediately.

Male Subjects

The effect of *(experimental drug*) on sperm has not been determined. Male patients should take the same precautions described above to avoid getting their partner pregnant.

All Subjects

In order to participate in this study, your child/ward must use reliable birth control methods, such as: *(Please list those methods that are medically reliable.)*

Payment for Being a Part of this Research Study (Choose the statement that fits.)

Since your child/ward may experience some inconvenience by taking part in this research study, you will be paid (*list the amount of money, other compensation, payment schedule, contingencies for payment, etc.).*

Neither you nor your child/ward will receive any cash or other benefits for taking part in this research study.

Costs of Being a Part of this Research Study

You *(will/will not)* be responsible for paying *(hospital/outpatient/other*) costs of participation in this research project. Hospital costs include *(describe)*. Outpatient costs include *(describe*). Other costs include *(describe).*

You *(will/will not*) have to pay certain fees for tests in the research study that are not a part of regular medical care for your child's/ward's condition. These extra tests and procedures add approximately *($ Added Cost*) to your child's cost of treatment. A research coordinator will discuss these additional expenses with you.

In Case of Illness or Injury

Call one of the doctors listed on the first page at *[Please fill in telephone number(s).]* in the event your child/ward gets sick or injured while on this study. If you have an emergency, go to the closest emergency room or clinic for treatment.

North Dakota Department of Human Services' Injury Statement

In the event that your child/ward sustains an injury or illness as a result of participating in this research, please be aware that medical treatment for the injuries or illness may not be available from the North Dakota Department of Human Services (DHS). DHS does not maintain an emergency department nor does it provide medical treatment in all disciplines of medicine. If your child/ward becomes ill or sustains an injury which you believe is related to participation in this research, **immediately** contact one of the persons listed on page 1 of this form, and if emergency care is needed seek emergency attention from your nearest local hospital.

If you believe your child/ward is injured as a result of participation in this research and the negligent conduct of a Department employee, you may notify the North Dakota Department of Human Services' Risk Manager at 701-328-2311, who will investigate the matter.

Sponsor Statement

(If applicable, insert Sponsor Statement here.)

Confidentiality of Your Child's/Ward's Records

Your child's/ward's research records will be kept *(Describe how)* to protect you privacy to the full extent of the law. However, authorized research investigators, agents of the United States Food and Drug Administration, the Department of Health & Human Services, the North Dakota Department of Human Services' Institutional Review Board, and other entities/individuals as required or authorized by law, may inspect your child's/ward's records from this research project. Doctors, nurses and others involved with your child's/ward's care will also be able to see the research information in your child's/ward's medical record.

Employees of *(sponsor's name)* who supply *(experimental drug)* will also have the right to look at your child's/ward's hospital record.

The results of this research study may be published, but they will not include your child's/ward's name or any other information that may identify your child/ward.

Volunteering to Be Part of this Research Study

Your child/ward should only take part in this research study if you want your child/ward to take part. If you choose not to have your child/ward participate, there will not be any penalty or loss of benefits to which your child/ward is otherwise entitled. If you decide that you want your child/ward to stop taking part in the study tell a study monitor as soon as possible. They will want to tell you if there are any dangers in stopping treatment and talk about other treatment(s) for your child's/ward's disease. Your child/ward may be removed from the study without your consent if: *(describe; new information presented from the sponsor, noncompliance, etc.).*

Questions and Contacts

If you/your child/ward have any questions about this research study, contact *(identify person(s) and their telephone numbers.)*

If you/your child/ward have questions about your child's/ward's rights as a person who is taking part in a research study, you may contact the Chair of the North Dakota Department of Human Services' Institutional Review Board, Dr. Christine Kuchler, at 1-888-328-2662.

Minor Consent—By signing this form I agree that:

I have fully read or have had read and had explained to me in language that I understand this informed consent form describing a research project.

I have had the opportunity to question one of the persons in charge of this research and have received satisfactory answers.

I understand that my child/ward is being asked to participate in research. I understand the risks and benefits, and I freely give my consent to have him/her participate in the research project outlined in this form, under the conditions indicated in it.

I understand that my child/ward is being asked to participate in research. I understand the risks and benefits, and I freely give my consent to have him/her participate in the research project outlined in this form, under the conditions indicated in it.

I will be given a signed copy of this informed consent form, which is mine to keep.

Signature of Parent/Legal Guardian	Printed Name	Date

Child's/Ward's Assent Statement

Dr._____ has explained the research study called:_____

_____

to me. I agree to be in this study.

Signature of Child/Ward	Printed Name of Child/Ward	Date

Signature of Parent/Legal Guardian	Printed Name	Date

Signature of Investigator	Printed Name of Investigator	Date

Signature of Witness	Printed Name of Witness	Date

OR

(Insert name of child/ward here.) is unable to give assent for the following reason(s):

Signature of Parent/Legal Guardian	Printed Name	Date

Signature of Investigator	Printed Name of Investigator	Date

Signature of Witness	Printed Name of Witness	Date

Investigator Statement

I have carefully explained to the subject the nature of the above protocol. I, hereby, certify that to the best of my knowledge the subject signing this consent form understands the nature, demands, risks and benefits involved in participating in this study and that a medical problem or language or educational barrier has not precluded a clear understanding of the subject's involvement in this study.

Signature of Investigator	Printed Name of Investigator	Date

Institutional Approval of Study and Informed Consent

This research project/study and informed consent form were reviewed and approved by the North Dakota Department of Human Services' Institutional Review Board for the protection of human subjects. This approval is valid until the date provided below. The board may be contacted at 1-888-328-2662.

Consent Form Approval Date:

Approval Consent Form Expiration Date: (*Your proposed expiration date is subject to IRB review.)*

- If this informed consent form has an "approval expiration date" that expires before the completion of this research study, the Principal Investigator may contact you for your re-consent at the time of expiration.